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Datasheet for the decision of 22 September 2010

Case Number: T 0261/08 - 3.3.04

Application Number: 90916891.6

Publication Number: 0512997

IPC: C12P 7/64

Language of the proceedings: EN

Title of invention:
Process for the heterotrophic production of products with high concentrations of omega-3 highly unsaturated fatty acids

Patentee:
MARTEK BIOSCIENCES CORPORATION

Opponents:
Nagase Biochemicals, Ltd
SANOFI-AVENTIS DEUTSCHLAND GMBH

Headword:
Omega-3 highly unsaturated fatty acids/MARTEK BIOSCIENCES CORPORTION

Relevant legal provisions:
EPC Art. 54, 56, 83, 107

Keyword:
"Sole request: novelty (yes); inventive step (yes); sufficiency of disclosure (yes)"

Decisions cited:
G 0004/88, G 0004/97, T 0343/01

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0261/08 **-** 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 22 September 2010

AppellantI: (Patent Proprietor)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 13 December 2007 concerning maintenance of European patent No. 0512997 in amended form.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: R. Gramaglia
G. Alt

Summary of Facts and Submissions

I. European patent No. 0 512 997, based on application No. 90916891.6 (published as WO 91/07498) and having the title "Process for the heterotrophic production of products with high concentrations of omega-3 highly unsaturated fatty acids" was granted on the basis of 36 claims.

II. Notices of opposition against the present patent were filed by Opponents O1 and O2 on the grounds of Articles 100(a), 100(b) and 100(c) EPC.

III. While the opposition division did not admit into the proceedings a new main request and auxiliary requests 1 to 3, filed during the oral proceedings on 12 December 2000, on the grounds of "prima facie serious defects", it decided that the patent could be maintained in amended form according to "auxiliary request 4", also filed during the oral proceedings.

IV. A first batch of appeals against the decision of the Opposition Division were lodged by the patent proprietor and opponent O2.

V. The present Board in a different composition decided in its decision T 0343/01 of 12 May 2005 that the Parties should have been heard on these "prima facie serious defects" identified by the Opposition Division in relation to the Proprietor's main request and auxiliary requests 1 to 3. The case was therefore remitted to the first instance for further prosecution (Article 111(1) EPC).

VI. The Opposition Division decided on 13 December 2007 that the claims of the main request lacked novelty and that the grounds for opposition did not prejudice the maintenance of the patent in amended form on basis of auxiliary request 1 filed during the oral proceedings on 12 December 2000.

VII. Claims 1, 8, 9, 10, 12, 28 and 29 of the auxiliary request 1 accepted by the Opposition Division read as follows:

"1. A food product, comprising:

(a) microorganisms of the genus Thraustochytrium, microorganisms of the genus Schizochytrium or mixtures thereof, wherein said microorganisms are capable of effectively producing omega-3 highly unsaturated fatty acid, and wherein the microorganisms are cultured in a culture medium to effectively produce omega-3 highly unsaturated fatty acid under conditions comprising:

(i) a salinity level yielding conductivities from 5 to 40 mmho/cm; and
(ii) a temperature of from 15°C to 48°C;

and

(b) wherein said microorganisms are incorporated with an additional animal or human food material."

"8. A method of raising an animal, comprising feeding said animal microorganisms as defined in claim 1, in an amount effective to increase the content of omega-3 highly unsaturated fatty acids in said animal."

"9. A food product, comprising the flesh of an animal, wherein said animal is raised by the method according to claim 8."

"10. A food product, comprising an egg, wherein said egg is from poultry raised by the method according to claim 8."

"12. A method of producing omega-3 highly unsaturated fatty acids, comprising culturing Thraustochytriales in a medium comprising a source of organic carbon, and a source of assimilable nitrogen, a salinity level of from 5 to 40 mmho/cm, and a temperature of from 15°C - 48°C."

"28. A unicellular microorganism selected from microorganisms having the identifying characteristics of Thraustochytriales ATCC number 20888, Thraustochytriales ATCC number 20889, Thraustochytriales ATCC number 20890, Thraustochytriales ATCC number 20891 and Thraustochytriales ATCC number 20892."

"29. Use of microorganisms selected from Thraustochytrium, Schizochytrium, mixtures thereof for the preparation of a composition for the treatment of disease selected from cardiovascular diseases, inflammatory and/or immunological diseases and cancer, wherein said microorganisms are capable of effectively producing omega-3 highly unsaturated fatty acid under conditions of a salinity level of from 5-40 mmho/cm and a temperature of from 15°C-48°C and wherein said microorganisms are cultured under conditions of a

salinity level of from 5-40 mmho/cm and a temperature of from 15°C—48°C."

Claims 2 to 7 related to specific embodiments of the food product according to claim 1. Claim 11 related to a specific embodiment of the method according to claim 8. Claims 13 to 27 related to specific embodiments of the method according to claim 12.

VIII. The Patentee (AppellantI) and opponent O2 (AppellantII) filed appeals against the decision of the opposition division. Opponent O1 is party as of right to the appeal proceedings according to Article 107 EPC.

IX. Together with the statement setting out the grounds of appeal, Appellant I filed a main request and auxiliary request 1, the latter being identical to that accepted by the opposition division. Further auxiliary requests 2 to 7 were submitted with Appellant I's letter dated 6 July 2010.

X. The following documents have been cited in the present decision:

D1 WO-89/00606;

D2 WO-88/10112;

D3 Bahnweg G., Veröff. Inst. Meeresforsch. Bremerh., Vol. 17, pages 245-268 (1979);

D4 Patent Abstracts of Japan, Application Number 63040711 (SUNTORY LTD.);

D5 Yongmanitchai W. et al., Process Biochemistry, August 1989, pages 117 to 125;

D6 Ellenbogen B.B. et al., Comp. Biochem. Physiol., Vol. 29, pages 805-811 (1969);

D7 R.A. Horne, Marine Chemistry, Wiley & Sons, pages 150-163, and 486-487 (1969);

D9 Declaration of Dr. K. Schaumann dated 7 December 2000 in relation to salinity and conductivity measures;

D11 Mackereth F.J.H. et al., Water Analyses, Freshwater Biological Association, page 47 (1978);

D13 Jones E.B.G., Recent Advances in Aquatic Mycology, Elek Science, London, pages 261, 262, 266 and 268-272 (1976);

D16 Wetzel R.G., Limnology, W.B. Saunders Company, pages 142-165 (1975);

D22 Barclay W. et al., World Rev. Nutr. Diet. (Karger, Basel), Vol. 83, pages 61-76 (1998);

D29 Comparison between the Examples of EP 0512997 (contested patent);

D31 First Declaration of Dr William R. Barclay dated 11 March 2005;

D33 Second Declaration of Dr William R. Barclay dated 14 September 2007;

D37 Schneider J., "Zur Taxonomie, Verbreitung und Ökologie einiger mariner Phycomyceten", aus dem Institut für Meerekunde an der Universität Kiel, pages 316-327 (1969;

-- Agreement dated 14 April 2000 between Aventis Research & Technologies GmbH & Co KG and Axiva Gmbh;

Z4 Notarially attested declaration of Klaus Menken and Joost Dwerhagen 9 April 2009;

Z9 Declaration of Klaus Dörr of 4 May 2009;

Z10 Declaration of Thomas Kiy of 20 May 2009;

Z11 Declaration of Matthias Rüsing of 7 May 2009;

Z12 Declaration of Stephan Hausmanns of 11 May 2009;

Z13 Declaration of Stephanie Müller-Broich of 6 May 2009;

Z18 Declaration of Gabriele Ahrens of 4 May 2010;

Z20 Further declaration of Stephanie Müller-Broich of 1 July 2010.

XI. Oral proceedings were held on 22 September 2010, during which Appellant I withdrew its appeal, with the result that its auxiliary request 1 became its sole request.

XII. The submissions by Appellant I, insofar as they are relevant to the present decision, can be summarized as follows:

Admissibility of the appeal by Appellant II

– Appellant II's appeal was inadmissible because the opposition it had begun was transferred to Axiva GmbH by the agreement dated 14 April 2000 together with the business assets in the interest of which the opposition had been filed as envisaged by the decision G 4/88 of the Enlarged Board of Appeal. The original opponent Aventis Research & Technologies GmbH & Co KG had then ceased to exist on 18 June 2003 and could not validly file an appeal on 2 February 2008. Thus, at the date of filing of the appeal, the party entitled to do so was Lonza Limited as the ultimate owner of the business assets in whose interest the appeal had been filed. In answer to a question from the Board, Appellant I agreed that G 4/88 did not hold that oppositions must be transferred together with the relevant business assets.

Article 83 EPC

– The patent in suit contained enough information in order to allow the skilled person to rework the invention, in particular to find an appropriate sample containing the microorganism required by claim 1. Also the information on the screening tests was very detailed. Moreover, the skilled person confronted with the measurement of the

conductivity would consider the most usual standard temperature of 25°C.

Article 56 EPC

– There was no hint in document D1 that the salinity of the growth medium could be lowered in order to reduce corrosion problems during the preparation of omega-3 highly unsaturated fatty acids (hereafter: HUFAs).

– Document D3 failed to mention any production of omega-3 HUFAs, while there was only one passage in document D13 which referred to omega-3 HUFAs. However, no information was given as to the total lipids or the total omega-3 HUFAs production per dry weight of cells.

– The skilled person consulting document D6 would be taught that these micro-organisms were "obligate marine species", implying that only seawater or artificial seawater had to be used as a medium.

– As for claims 8 to 12, the same closest prior art as for claim 1, namely document D1, had to be taken for the problem/solution analysis.

XIII. The submissions by Appellant II, insofar as they are relevant to the present decision, can be summarized as follows:

Admissibility of its appeal

– A complete chain of succession can be shown from Aventis Research & Technologies GmbH & Co KG to Sanofi-Aventis Deutschland GmbH. As the declaration document Z4 explains, Aventis Research & Technologies GmbH & Co KG (until 29 May 1988 called Hoechst Research & Technology Deutschland GmbH & Co KG) was a limited partnership of Hoechst AG and Hoechst Research & Technology Deutschland Verwaltungs GmbH (which changed its name to Aventis Research & Technologies Verwaltungs GmbH on 4 November 1988). When Hoechst AG withdrew from the partnership, it was dissolved and all its assets and obligations were transferred by operation of law to the other partner, Aventis Research & Technologies Verwaltungs GmbH, with effect from 31 May 2003 and as registered in the Handelsregister on 18 June 2003. On 29 August 2003 Aventis Research & Technologies Verwaltungs GmbH was merged into Aventis Pharma Deutschland GmbH which on 1 September 2005 changed its name to Sanofi-Aventis Deutschland GmbH.

– As regards the agreement of 14 April 2000, Appellant II agrees that business assets relating to ***inter alia*** fatty acids were transferred to Axiva GmbH and that oppositions, including the current opposition, were referred to therein. However, the agreement also provided (in clause 6.1) that if formal transfer of an opposition might not be possible, Axiva GmbH was permitted to continue to conduct the opposition in the name of Aventis Research & Technologies GmbH &

Co KG. As several declarations show, it was subsequently decided to do this because the parties were unsure whether the conditions for recording a transfer had been fulfilled and also because at the time the agreement with Axiva GmbH was seen as an interim arrangement (see the declarations, documents Z9 to Z13). Axiva GmbH and its successors in business dealt with the opposition, and subsequently the appeal proceedings, they gave the representative instructions and settled her charges, but the opposition continued in the name of the original opponent. At the time the appeal was filed in 2008, the representative was unaware of the events by which Sanofi-Aventis Deutschland GmbH had become the universal successor to Aventis Research & Technologies GmbH & Co KG and thus the appeal was filed in that name (see the declarations, documents Z18 and Z20).

Article 83 EPC

– The patent did not contain enough information to allow the skilled person to obtain further microorganisms of the genus Thraustochytrium or Schizochytrium referred to in the claims.

– Even if the sample could be found, the skilled person failed to rework the invention, since the temperature for the measurement of the conductivity was not specified.

Article 56 EPC

- The feature in claims 1 and 8 and implicitly in claims 9 and 10, relating to the culture conditions of the micro-organisms did not achieve any effect on the claimed product or process. Therefore this feature could be overlooked for the purpose of deciding inventive step.

- Claim 1 lacked an inventive step starting from document D4 as closest prior art in combination with document D1, or vice versa.

- Claim 8 lacked an inventive step starting from document D2 as closest prior art in combination with document D1.

- The only difference between the method of claim 8 and that described in document D2 lay in the source of omega-3 HUFAs. Hence the skilled person would turn to document D1, disclosing microorganisms of the genus Thraustochytrium or Schizochytrium as HUFA producers.

- The only difference between the food product of claims 9 and 10 and that described in document D2 (or in document D4) or the "food chain" referred to in document D5 lay in the source of omega-3 HUFAs. Hence, the skilled person would turn to document D1, disclosing microorganisms of the genus Thraustochytrium or Schizochytrium as HUFA producers. The skilled person would have combined these teachings.

– As for the process according to claim 12, Table 1 of document D6 reported the high levels of omega-3 HUFAs in three Thraustochytriales (T. roseum, T. aureum and T. aggregatum), whereas documents D3 and D13 showed the capacity of Thraustochytriales to grow in media of very low salinities. The skilled person would have combined these teachings.

XIV. Appellant I (Patentee) requested that Appellant II's appeal filed in the name of "Aventis Research & Technologies GmbH & Co KG" be deemed inadmissible or, by necessary implication after withdrawing its own appeal (see Section XI above), that Appellant II's appeal be dismissed.

Appellant II (Opponent 02) requested that its notice and statement of grounds of appeal be corrected to show the name of the Opponent 02 and Appellant II as "Sanofi-Aventis Deutschland GmbH" and that the decision under appeal be set aside and the patent be revoked.

Reasons for the Decision

Admissibility of Appellant II's appeal

1. Appellant I rests its objection to the admissibility of Appellant II's appeal on two arguments. First, it says the opposition filed by Opponent 02, Aventis Research & Technologies GmbH & Co KG, was transferred to Axiva GmbH because the assets in the interest of which the opposition was filed were transferred to Axiva GmbH by the agreement of 14 April 2000 and this must follow from the decision G 4/88 (OJ 1989, 480). Second, it

argues that Aventis Research & Technologies GmbH & Co KG could not validly file an appeal on 2 February 2008 because it had ceased to exist on 18 June 2003.

2. The two arguments could in principle be independent of each other because, even if the opposition was not transferred to Axiva GmbH, a non-existent Opponent cannot file an appeal. However, it appears that Appellant I does not see them as independent since it also says, by way of conclusion to its arguments, that the only correct Appellant in February 2008 could have been Lonza Limited which, it alleges, had by then become the owner of the relevant business assets after two further transfers. Further, the fact that Appellant I made no attempt to argue against Appellant II's case that Sanofi-Aventis Deutschland GmbH is the universal successor to Aventis Research & Technologies GmbH & Co KG, shows that it regards the first argument as the key to its objection. In any event, the second argument can be disposed of swiftly. The Board is satisfied by the evidence filed by Appellant II (see in particular the notarially attested declaration Z4) that Sanofi-Aventis Deutschland GmbH is in fact the universal successor to Aventis Research & Technologies GmbH & Co KG. Thus the remaining question is whether or not the assets and obligations which Sanofi-Aventis Deutschland GmbH acquired as universal successor included the opposition begun by Aventis Research & Technologies GmbH & Co KG. The Board has no doubt that it did.

3. Appellant I's argument that the opposition was transferred to Axiva GmbH because assets relating to the opposition were transferred pre-supposes that, whenever such assets are transferred, any related

opposition is also transferred. No case-law was cited by Appellant I until the oral proceedings when G 4/88 was cited, although the phrasing of the letter of 16 April 2009 in which the inadmissibility objection was made shows clearly that G 4/88 was relied on. However, as Appellant I agreed at the oral proceedings, G 4/88 did not hold that oppositions **must** be transferred together with the relevant business assets, only that they can. The question put to the Enlarged Board in G 4/88 was:

"Is an opposition pending before the European Patent Office transferable only to the opponent's heirs or **can** it be transferred freely either with the opponent's enterprise or with a part of that enterprise operating in a technical field in which the invention to which the patent in suit relates can be exploited?" (Emphasis added)

The Enlarged Board's answer to that question (see the Order and Headnote) was:

"An opposition pending before the European Patent Office **may** be transferred or assigned to a third party as part of the opponent's business assets together with the assets in the interests of which the opposition was filed." (Emphasis added)

Thus the conclusion was that, in the circumstances considered by the Enlarged Board, an opposition could be transferred - such a transfer being possible but not mandatory. Those circumstances were carefully defined by the Enlarged Board (see Reasons, points 5 and 6) which stated it was not considering whether an

opposition could be transmitted or assigned independently of the existence of an interest in instituting the opposition but only the situation in which the opposition has been instituted in the interest of the opponent's business or part of that business. Although, in that limited situation, the Enlarged Board considered that the opposition constitutes an "inseparable part" of those assets, it then proceeded to state that:

"insofar as those assets are **transferable or assignable** under the applicable national laws, the opposition which is part of them must also be regarded as **transferable or assignable** in accordance with the principle that an accessory thing when annexed to a principal thing becomes part of the principal thing." (Emphasis added)

4. Thus the Enlarged Board expressly excluded consideration of any transfer of an opposition independently of related business assets, limited the principle it enunciated to the situation where the opposition has been instituted in the interest of the opponent's business or part of that business, subjected the application of that principle to the possibility of transfer under national laws, and held that even then a transfer was possible but not mandatory. On the one hand, Appellant I has not shown how the alleged transfer of opposition falls within these limitations and, in agreeing the last of them, made it impossible to do so. On the other hand, Appellant II has produced evidence which demonstrates not only that the case does not fall within those limitations but that in fact there was no transfer. Thus, while the agreement of

14 April 2000 certainly transferred assets, and even contemplated a transfer of the opposition in question, it also provided a mechanism (in clause 6.1 of the agreement) whereby it would not be transferred but remain in the name of the original opponent. That mechanism was then used with the result that, while Axiva GmbH and its successors in business actually prosecuted the opposition, the original opponent remained such. The reasons advanced for this - uncertainty whether the conditions for a transfer were met and over the future of the business - are, while immaterial for present purposes, plausible as commercial considerations. The result may have been that the opponent became a purely nominal opponent but that is no different from a "straw man" opponent which is permissible throughout opposition and appeal proceedings (see G 4/97 OJ EPO 1999, 270). Indeed, unlike the "straw man" situation, there was no attempt to conceal the identity of the third party behind the nominee as is evidenced by the fact that Appellant II obtained a copy of the agreement of 14 April 2000.

5. Thus the Board finds that there was no transfer as alleged by Appellant I from Aventis Research & Technologies GmbH & Co KG to Axiva GmbH. Subsequent transactions involving Axiva GmbH and its successors in business have no relevance. The opposition remained in the name of Aventis Research & Technologies GmbH & Co KG as long as that company existed and was then transferred by way of universal succession first to Aventis Research & Technologies Verwaltungs GmbH and then to Sanofi-Aventis Deutschland GmbH.

Appellant II's request to record a change of name

6. Appellant II requested in one of its two letters of 15 July 2010 that the name of Opponent 02/Appellant II be corrected to Sanofi-Aventis Deutschland GmbH. It appears to the Board that the request should rather be to record the name of a new opponent as a result of two transfers by universal succession. The outcome is of course the same whatever the nature of the request and, since the Board has found in the context of Appellant I's inadmissibility objection that there has been such a transfer and that it included the opposition in question, the request is allowed.

Sufficiency of disclosure

7. Appellant II argued that the patent did not contain enough information in order to allow the skilled person to reproduce the invention across the whole claimed range due to a lack of information as to how to obtain microorganisms of the genus Thraustochytrium or Schizochytrium other than the deposited ones (see claim 28 in paragraph VII supra) meeting the salinity and temperature criteria referred to in the claims. In Appellant II's opinion, the presence of these microorganisms in a sample was a random event and hence it represented an undue burden to find an appropriate sample containing by chance further microorganisms of the genus Thraustochytrium or Schizochytrium having the same properties of the deposited strains and then to perform several screening tests.

8. The Board observes that the patent in suit (see page 5, line 54 to page 6, line 56) provides a very detailed

screening method for arriving at the subject microorganisms which can produce omega-3 HUFAs at a particular salinity level and temperature range.

The skilled person is taught that suitable strains are wide spread in the habitats listed on page 5, line 57 to page 6, line 3 of the patent.

The patent further provides on page 6, lines 6 to 16 the information how to select these microorganism in size by means of a "sandwich" filtration involving two types of filters having pore sizes of 25 µm (top) and 1.0 µm (bottom), respectively. A comparison between Figures 1A and 1B annexed to Declaration D33 indeed shows that this way to proceed is appropriate for obtaining microorganisms of the genus Thraustochytrium and/or Schizochytrium: Fig. 1A is an image of the cultured portion of the sample that has merely been selected for microorganisms greater than 1 µm in size but not "sandwich" filtrated to exclude unicellular and pluricellular microorganisms having a size greater than 25 µm, and Fig. 1B is an image of the cultured portion of the sample that has been selected for microorganisms from 1 to 25 µm in size via "sandwich" filtration involving two types of filters. As is apparent from the images (see also paragraph 7 of Declaration D33), the culture portion of Fig. 1A exhibits a thick mat of several intertwined layers of microorganisms grown over the filter that precludes accessing further colonies of microorganisms for selection, whereas the culture portion of Fig. 1B is highly enriched for the microorganism looked for.

The patent (see page 6, lines 21 to 56) also describes the way to further proceed by growing the cultures in the dark under high temperature and low salinity conditions, picking the white colonies (except for the yeast-type colonies), further growing in the dark at high temperature and analysing the selected strains for omega-3 HUFAs by gas chromatography.

9. Appellant II also criticises the Examples of the patent as casting doubt on the capacity of the selected strains to produce omega-3 HUFAs within the whole range of temperature and salinity stated in claim 1. In the Appellant II's opinion, Example 1 lacked any information as to where the sample had been collected and as to the salinity used. Furthermore, selection occurred only at 30°C, without testing temperature tolerance (see page 13, lines 9 to 15 of the patent). Examples 2 to 5 used cultivation media M5 and FFM exhibiting the salinity of seawater.

10. However, in the Board's view, Example 1 states that the sample was collected from a "shallow inland saline pond", in keeping with the list given on page 5, line 57 to page 6, line 3 of locations where samples can be taken. As for the salinity of the culture, this is clearly that of diluted seawater (see page 13, line 1: 600 ml seawater + 400 ml distilled water). The screening takes place at a temperature within the claimed range, and Example 1 further states that salinity tolerance can be screened for in a similar way (see line 22). In fact, the purpose of Example 8 is to investigate such salinity tolerance.

11. As for the "high salinity" of the cultivation media used in Examples 2 to 5, the Board notes that said Examples deal with investigations other than the screening, the relevant strains having already gone through a screen in which growth and production of omega-3 HUFAs had been reviewed at the claimed temperature and salinity. In any event, the patent also comprises Examples 8, 9 and 13 to 15 dealing with investigations of the micro-organisms' behaviour in "low salinity" cultivation media (see "LS" in the first column of the Table of document D29).

12. Appellant II also maintains insufficiency in respect of the measurement of conductivity, arguing that the temperature for the measurement of the conductivity was not specified in the patent in suit and pointing out that the conductivity of a solution strongly depended on temperature (see document D7, page 487, Table A-11).

As regards the temperature at which conductivity had to be measured, the Board considers that the skilled person was aware that 25°C was the most frequently used standard reference temperature for measuring the conductivity of a solution. This view is supported by (i) document D7 (see page 163, line 4 under "The Types of Species in Seawater" highlighting that 25°C represented the standard temperature at which to measure the constituents of seawater; by (ii) the fact that in declaration D9, submitted by Appellant II, the conductivity of water has been measured at 25° C (see bottom of page 1: "K_{25} = 0.055 µS.cm^{-1}"; emphasis added); by (iii) document D11 (page 47, line 25) and by (iv) document D16 (see page 148, end of first paragraph:

"The international chemical standard reference of 25°C is recommended in all cases...").

13. In view of the foregoing, the Board considers that no case of insufficiency of disclosure has been made out.

Novelty

14. At oral proceedings, Appellant II did not raise any objection of lack of novelty against the claims of the first auxiliary request and the Board also sees none.

Inventive step
Claim 1
Closest prior art

15. Claim 1 is directed to a food product comprising omega-3 fatty acid-producing Thraustochytrium and/or Schizochytrium, cultured under the conditions set out in claim 1, and an additional animal food material.

Document D1 discloses that certain Thraustochytriales (this term includes both Thraustochytrium and Schizochytrium) produce omega-3 HUFAs when cultured in seawater (see Example 1), or in artificial seawater (see Example 3) and that these fatty acids extracted from these microorganisms can be used in food products as food additives (see claim 12).

Document D2 is concerned with the administration of omega-3 HUFAs to poultry for increasing the omega-3 HUFA content of their flesh/eggs. No reference is made to the micro-organisms.

Document D4 teaches that inexpensive animal feed can be manufactured by incorporating into the feed material microbial cells of the genus, inter alia, Mortierella or Conidiobolus containing omega-3 HUFAs such as eicosapentaenoic acid (EPA).

Document D5 discloses microorganisms, including Thraustochytrids and Schizochytrids, as a source of highly unsaturated omega-3 HUFAs (see page 121, Table 1). It can be derived from document D5 that fish which have been eating Traustochytrium and Schizochytrium during their life have accumulated omega-3 HUFAs in their flesh.

16. The analysis above shows that the animal food referred to in document D1 differs from the claimed food product by the fact that Thraustochytrium and Schizochytrium are not incorporated as such into the food. The food product described in document D4 also differs from the claimed product (Mortierella or Conidiobolus instead of Thraustochytrium or Schizochytrium). However, as regards the culture conditions set out in claim 1, document D1 prescribes seawater (see point 23 infra), whereas document D4 is silent as to any conditions at which omega-3 HUFAs should be produced. In view of this, the Board considers that document D1 represents the closest prior art.

17. Appellant II considers that the feature in claim 1 relating to the culture conditions of the micro-organisms (a salinity level yielding conductivities from 5 to 40 mmho/cm and a temperature of from 15°C to 48°C) does not achieve any effect on the chemical composition of the claimed food product. Therefore, in

the Appellant II's view, this feature in claim 1 can be overlooked for the purpose of deciding inventive step, as it does not add anything to the micro-organisms' capacity of producing omega-3 HUFAs already stated in claim 1.

18. However, in view of Annex 1 to Declaration D31, the Board is of the opinion that the salinity of the medium in which Thraustochytrium and Schizochytrium grow influences the fatty acid composition pattern of the micro-organisms. This has not been disputed by Appellant II, when arguing (see page 17, lines 4-6 from the bottom of its submissions dated 19.08.2010) that ATCC 20888 and ATCC 28209 referred to in said Annex 1 produce more HUFAs at low salinities. In conclusion, the feature in claim 1 relating to the culture conditions of the micro-organisms cannot be overlooked for the purpose of deciding the inventive step.

Problem to be solved

19. According to Example 8 of the patent, in particular on page 25, lines 5-8, the problem to be solved lies in avoiding corrosion and disposition problems occurring in the fermentation step with seawater. The proposed solution consists in using a less saline culture medium as set out in claim 1.

20. The relevant question is whether or not this proposed solution follows from the prior art in an obvious manner.

21. Appellant II maintains that claim 1 lacks an inventive step starting from document D4 as closest prior art and

combining with document D1, or vice versa. Document D4 taught the skilled person animal feed incorporating the highly unsaturated fatty acid producing micro-organisms Mortierella or Conidiobolus. The only difference lay in the source of omega-3 HUFAs´ producers. Therefore, the problem to be solved was the provision of an alternative animal food, incorporating different micro-organisms.

22. In the Board's judgement, even if the skilled person combined the teachings of documents D4 and D1, there was no hint in document D1 that the salinity of the growth medium could be lowered in order to reduce corrosion problems during the preparation of omega-3 HUFAs.

23. Document D1 taught that obligately freshwater (aquatic) heterotrophic eukaryotes did not produce omega-3 HUFAs (see page 4, lines 8-16) and that omega-3 HUFAs appeared to be produced only by marine organisms or by halophilic or halo-tolerant species (page 4, line 34 to page 5, line 3). All the Examples in document D1 used a medium having the salinity level of seawater. Examples 4 and 5 dealt with variations of the culture conditions (action of light, addition of N and P), however, not with variations of salinity, suggesting that the authors of document D1 did not even think of modifying salinity. In conclusion, document D1 taught the skilled person to use natural seawater or to make up a solution which was equivalent to seawater. There was no teaching in document D1 about reduced salinity, let alone about corrosion problems arising during the preparation of omega-3 HUFAs.

24. Appellant II maintains that the skilled person would inevitably have turned to documents D3 or D13 teaching cultivation of Thraustochytriales at low salinity. Document D3 established the capacity of Thraustochytriales to grow in media of very low salinities (see Fig. 11-14), whereas Table 10.5 on page 270 of document D13 illustrated the "salinity tolerance" (i.e. the capacity to grow at low salinities) of Thraustochytrium and Schizochytrium. The skilled person faced with corrosion problems arising during the preparation of omega-3 HUFAs would have thus been motivated to use these low salinities to reduce fermenter corrosion.

25. The Board observes that document D3 fails to mention any production of omega-3 HUFAs, be it at high or low salinities. Therefore, the skilled person attempting to solve a problem pertaining to the reduction of fermenter corrosion during omega-3 HUFAs's production could not draw any useful information from this document.

26. As for document D13, the latter is a review (published 13 years earlier than the priority date of the patent in suit) of academic papers dealing with taxonomy, morphology, ecology and physiology relating to growth of Thraustochytriales. There is only one passage which refers to omega-3 HUFAs on page 272 of document D13 ("Ellenbogen et al. (1969) have shown that T. aureum, T. roseum, Schizochytrium aggregatum and Dermocystidium sp. can synthesize polyunsaturated fatty acids of the ω6 (linoleic) and the ω3 (α-linoleic) groups"). However, no information is provided as to the total fatty acid or the total omega-3 HUFAs production per dry weight of

cells. Moreover, the skilled person consulting Ellenbogen (document D6) would be taught that these micro-organisms were "obligate marine species" (see under "Material and Methods"), implying that only seawater or artificial seawater had to be used as a medium. This view is supported by document D5 (see page 118, end of r-h column), which highlights the importance of using seawater ("In cultivation of marine micro-organisms, natural sea water is necessary, unless basal medium contains sufficient of all essential trace elements"). Appellant II also pointed to page 319 of document D37 as demonstrating that Schizochytrium aggregatum was known to grow at low salinities of 3.8-27 ‰. However, this document does not mention the production of omega-3 HUFAs and thus, the skilled person attempting to solve a problem pertaining to omega-3 HUFAs production could not draw any useful information from this document. Hence, the prior art led the skilled person away from arriving at microorganisms of the genus Thraustochytrium or Schizochytrium endowed with the property of producing high quantities of omega-3 HUFAs at low salinities.

27. In view of the foregoing, the Board concludes that the subject-matter of claim 1, directed to a food incorporating these micro-organisms, does not follow from the prior art in an obvious way. This conclusion also applies to the unicellular micro-organisms according to claim 28 and to the medical use according to claim 29, which is based on these micro-organisms, as well as to dependent claims 2 to 7.

Claim 8

28. Claim 8 relates to a method of raising an animal, comprising feeding the animal microorganisms as defined in claim 1, in an amount effective to increase the content of omega-3 HUFAs in the animal.

29. Appellant II argues that the feature in claim 8 relating to the culture conditions of the micro-organisms can be overlooked for the purpose of deciding the inventive step because the scope of claim 8 is to increase the omega-3 HUFAs in animals, i.e. something different from reducing fermenter corrosion. Therefore, the only difference between the claimed method and that described in document D2 (teaching the administration of omega-3 HUFAs to poultry for the same scope) lay in the source of omega-3 HUFAs. Hence Appellant II argues that the skilled person would turn to document D1, disclosing microorganisms of the genus Thraustochytrium or Schizochytrium as omega-3 HUFA producers.

30. The Board cannot agree that the feature in claim 8 relating to the culture conditions of the micro-organisms can be overlooked for the purpose of deciding the inventive step of claim 8. The Board has already decided that the skilled person would not have arrived in an obvious way at micro-organisms grown at low salinities (see points 15 to 27 supra). Therefore, the method of raising an animal according to claim 8, which relies on feeding animals these inventive micro-organisms, is also not obvious. This conclusion extends to dependent claim 11.

Claims 9 and 10

31. Claim 9 and 10 relate to the flesh of an animal or an egg from poultry, respectively, raised by the method according to claim 8.

By virtue of the reference therein to claim 8, Appellant II considers that claims 9 and 10 comprise the implicit feature that the claimed flesh/eggs is from animals/poultry fed with Thraustochytrium or Schizochytrium grown under culture conditions of low salinity. However, Appellant II asserts that this implicit feature (culture conditions of low salinity) can be overlooked for the purpose of deciding the inventive step because it has no effect on the final product. To buttress its view, Appellant II relies on Table 6 on page 70 of document D22 showing that the peaks of the omega-3 HUFas in the flesh/egg of an animal/poultry raised by the method according to claim 8 do not correspond to those of the omega-3 HUFAs produced by the micro-organism. Appellant II thus concludes that the only difference between the claimed food product and that described in document D2 (or in document D4) or the "food chain" referred to in Fig. 2 of document D5, lay in the source of omega-3 highly unsaturated fatty acids. Hence, the skilled person would turn to document D1, disclosing microorganisms of the genus Thraustochytrium or Schizochytrium as HUFA producers.

32. However, the Board notes that Table 6 in document D22 does not compare the peaks of the omega-3 HUFAs in the flesh/egg of an animal/poultry with those in the micro-organisms (but merely with those in the control animals

not fed with Schizochytrium). This Table thus does not support the Appellant II's proposition that a "shuffling" of the omega-3 HUFA peaks occurs during the passage from the micro-organism to the flesh/egg.

Rather, it has been accepted by Appellant II (see point 18 supra) that the micro-organisms produce different levels of omega-3 HUFAs at low compared with high salinity. Therefore, in the Board's opinion, it is reasonable to expect that this difference in the levels of omega-3 HUFAs reflecting that in the micro-organism of origin somehow persists in the animals' flesh/eggs (of course, only in the case of equality of both the feeding time and the quantity of fed Traustochytriales, grown at low salinity, compared with the same strain, grown at high salinity).

In conclusion, the implicit feature in claims 9 and 10 that the claimed flesh/eggs is from animals/poultry fed with Thraustochytrium or Schizochytrium grown under culture conditions of low salinity cannot be overlooked for the purpose of deciding the inventive step of claims 9 and 10 because the salinity of the medium in which Thraustochytrium or Schizochytrium grow influences the fatty acid composition pattern of the micro-organism and hence of the flesh/eggs, which thus keep a kind of "fingerprint" reflecting the composition in the micro-organism of origin. It is also not credible that a micro-organism producing twice as much omega-3 HUFAs than another micro-organism will lead to the same omega-3 HUFA levels in the animals'/poultry's flesh/eggs.

Consequently, once this implicit feature (culture conditions of low salinity) is taken into account, the conclusions of non-obviousness arrived at by the Board in point 30 supra also apply to present claims 9 and 10.

Claim 12

33. Claim 12 is directed to a method of producing omega-3 HUFAs, comprising culturing Thraustochytriales in a medium comprising, inter alia, a salinity level of from 5 to 40 mmho/cm.

34. The Board already decided (see point 26 supra) that the skilled person would not have arrived in an obvious way at microorganisms of the genus Thraustochytrium or Schizochytrium endowed with the property of producing high quantities of omega-3 HUFAs at low salinities (see points 15 to 27 supra). This conclusion extends to the method according to claim 12.

35. Appellant II developed a further line of argument for questioning the inventive step of claim 12, based on the combination of document D6 with document D13 or D3. Table 1 of document D6 (see also the term "large amounts" on page 805, under "Introduction") reported the high levels of omega-3 HUFAs in three Thraustochytriales (T. roseum, T. aureum and T. aggregatum), whereas documents D3 and D13 showed the capacity of Thraustochytriales to grow in media of very low salinities. However, the analysis of documents D6, D3 and D13 made in points 19 and 20 supra clearly shows that the skilled person had no incentive to cultivate Thraustochytriales in media of low salinities.

Consequently, the conclusions of non-obviousness arrived at by the Board in point 30 supra also apply to present claim 12 and dependent claims 13 to 27.

Order

For these reasons it is decided that:

1. The name of Appellant II is to be amended to read "Sanofi-Aventis Deutschland GmbH".

2. The appeal of Appellant II is dismissed.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith